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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,539	04/20/2004	Stanley L. Mills	362187-991221	3891

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EXAMINER	
LAMPRECHT, JOEL	
ART UNIT	PAPER NUMBER
3737	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/828,539	MILLS, STANLEY L.	
	Examiner	Art Unit	
	JOEL M. LAMPRECHT	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-12,17-20,25 and 26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

The priority of the instant application as set forth in the specification is out of date, and should be updated as to the status of the claimed priority documents.

Claim Objections

Claims 3, 4, 7-11, 15, 16, 18, 32, 38-42, and 45, are objected to because of the following informalities: Claim 3's dependency should be to claim 1, not to claim 21, as set forth on the amendment of 4/20/04 and it is unclear whether and where one or all of the radioisotopic components are part of the claimed invention as set forth. Regarding claims 7 and 8, it is unclear if the spacer element set forth is in addition to the one set forth in claim 5. Regarding claim 8, the term "sad" should be removed or replaced. Regarding claim 9, it is unclear if the spacer elements set forth are in addition to those set forth in claim 6. Regarding claim 10, the second use of the term "surfaces" should be singular, as well as the term "chambers". Regarding claims 15, 16, 18, 32 and 45, it is unclear what additional structural element has been set forth as the claims only relate to intended use or functional capability. Claims 38-42 are grammatically incorrect, and should read "each of the bubbles" or "each of the channels". Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3-12, 17-20, 25-26, 29, 33-42 and 45 are rejected under 35 U.S.C. 102(e) as being anticipated by Vitali et al (US 6,585,633 B2). Vitali et al disclose a medical device comprising a parabolic surface defining a body chamber (Fig 1), a radioisotopic component (including 125I or 103PD) inside the body chamber and separated from the parabolic surface in at least one location by a gap (Fig 1-2), a number of parabolic surfaces each defining a body chamber and being able to contain spacer elements (Fig 11, 16) the medical device having a proximal and distal end and the device being adapted for implantation into a live body (Fig 31-34). Vitali et al also disclose a number of spacer elements along the device which may be made of polyglectin (Fig 26, Col 4 Line 5-35), body chambers connected to spacer elements that are connected to a second chamber of the device (Fig 25-26), the existence of a contrast material inside the body chamber (Col 4 Line 6-35),a docking guild near the proximal end of the device for accepting radioactive sources or spacers comprising a flexible joint (Fig 25-28, Col 5 Line 30 – Col 6 Line 20), a non-locking docking port, and discloses the use of catgut as a spacer element within the device (Col 1 Line 50-65). Vitali et al also disclose a device containing one or more voids, bubbles or channels

including bubbles made of radioactive elements (Fig 2, Element 20), channels for the delivery of those said radioactive elements (Fig 14), and voids which may be filled with spacer elements (Fig 16, 15, and Figure 2 Element 18).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 13-16, and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vitali et al in view of McIntire et al (US 2002/0022781). Vitali et al disclose the invention as claimed including a medical device comprising a parabolic surface defining a body chamber (Fig 1), a radioisotopic component (including 125I or 103PD) inside the body chamber and separated from the parabolic surface in at least one location by a gap (Fig 1-2), a number of parabolic surfaces each defining a body chamber and being able to contain spacer elements (Fig 11, 16) the medical device having a proximal and distal end and the device being adapted for implantation into a live body (Fig 31-34). Vitali et al also disclose a number of spacer elements along the device which may be made of polyglectin (Fig 26, Col 4 Line 5-35), body chambers connected to spacer elements that are connected to a second chamber of the device (Fig 25-26), the existence of a contrast material inside the body chamber (Col 4 Line 6-35), a docking guild near the proximal end of the device for accepting radioactive

sources or spacers comprising a flexible joint (Fig 25-28, Col 5 Line 30 – Col 6 Line 20), a non-locking docking port, and discloses the use of catgut as a spacer element within the device (Col 1 Line 50-65). Vitali et al also disclose a device containing one or more voids, bubbles or channels including bubbles made of radioactive elements (Fig 2, Element 20), channels for the delivery of those said radioactive elements (Fig 14), and voids which may be filled with spacer elements (Fig 16, 15, and Figure 2 Element 18).

Vitali et al do not disclose a spacer element comprising a contrast material like silver, gold or tungsten or a device using LCP, metals such as titanium, and additionally does not mention specific monitoring of radioisotopic components in a patient; though the device is capable of such action, no reference is made to monitoring seed placement. Attention is then paid to the secondary reference by McIntire et al which discloses the use of a contrast material [0027], specifically silver for the carrier elements of the device for the purpose of making them x-ray detectable. McIntire et al also disclose the inclusion of titanium in the device [0008, and 0029] for the container materials. McIntire et al also provides reasoning and motivation for the inclusion of their device in the role of providing accurate position of the radioisotopic components in relation to the tissues of a patient [0009]. Finally McIntire disclose a number of additional polymers including Polypropylene, Polyethylene, and Polystyrene, all of which have specific gravities typically between .9 and 1.1 g/ml (From Modern Plastics Encyclopedia 99, p. B158 to-B216). It would have been obvious to one of ordinary skill in the art to have included the materials provided by McIntire et al with the brachytherapy seed delivery device of

Vitali et al for the purpose of providing the most accurate and easily imaged brachytherapy system.

Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vitali et al in view of Coniglione (US 6,347,443 B2). Vitali et al disclose all that is listed above but fail to mention specifically using LCP as a polymer contained in the device. Vitali et al do use a polymer but it is not liquid crystal polymer. Attention is then directed to the secondary reference by Coniglione in the same area of endeavor which describes LCP as an acceptable material along the lines of that which is used in Vitali et al for the construction of brachytherapy devices (Col 10 Line 25-50). It would have been obvious to one of ordinary skill in the art to have used the polymer disclosed by Coniglione in the brachytherapy device of Vitali et al for the purpose of providing a different nonabsorbable polymer for the construction of their brachytherapy device.

Response to Arguments

Applicant's arguments filed 12/5/08 have been fully considered but they are not persuasive. Applicant has first argued that the headpiece of Vitali is not of a parabolic nature, to which Examiner respectfully disagrees. A parabolic surface need only form a conical shape, and the headpiece of figure 1 of Vitali (See the large element 23) is conical on all sides as it tapers to the seed cartridge. The parabolic body chamber of Figure 1 comprises a gap (see the near portion of the element) from which the seeds are implanted into a live body. The radioisotopic components are implanted through the parabolic head of Vitali into the body. Applicant further argues that the device of Vitali is not adapted for implantation into a live body. As stated on page 7 of Applicant's

remarks, the radioisotopic seeds which are a part of the device of Vitali are implanted into a live by via the adaptations made to the device of Figure 1, meaning the device of Figure 1 is adapted for implantation into a live body (even if just the needles or the seeds).

Seed implantation: Radiation treatment given by placing radioactive material contained within a small cylindrical shell directly in or near the target, often a tumor. Medicine.net

Implantation: The process of placing something in the human body (medicine). Merriam Webster

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOEL M. LAMPRECHT whose telephone number is (571)272-3250. The examiner can normally be reached on 8:30-5:00 Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BRIAN CASLER/
Supervisory Patent Examiner, Art Unit 3737

JML